Claims

1. Method for in vitro detection of acute generalized inflammatory conditions (SIRS),

characterized in that

it comprises the following steps:

a)   Isolation of sample RNA from a sample of a mammal;

b)   Labelling of the sample RNA and/or at least one DNA being a gene or gene fragment specific for SIRS, with a detectable label.

c)   Contacting the sample RNA with the DNA under hybridization conditions;

d)   Contacting sample RNA representing a control for non-pathologic conditions, with at least one DNA, under hybridization conditions, whereby the DNA is a gene or gene fragment specific for SIRS;

e)   Quantitative detection of the label signals of the hybridized sample RNA and control RNA;

f)   Comparing the quantitative data of the label signals in order to determine whether the genes or gene fragments specific for SIRS are more expressed in the sample than in the control, or less.

2.   Method for in vitro detection of sepsis and/or sepsis-like conditions,

characterized in that

it comprises the following steps:

g)   Isolation of sample RNA from a sample of a mammal;

h)   Labelling of the sample RNA and/or at least one DNA being a gene or gene fragment specific for sepsis, with a detectable label.

i)   Contacting the sample RNA with the DNA under hybridization conditions;

j)   Contacting sample RNA representing a control for non-pathologic conditions, with at least one DNA, under hybridization conditions, whereby the DNA is a gene or gene fragment specific for sepsis and/or sepsis-like conditions;

k)   Quantitative detection of the label signals of the hybridized sample RNA and control RNA;

l)   Comparing the quantitative data of the label signals in order to determine whether the genes or gene fragments specific for sepsis and/or sepsis-like conditions are more expressed in the sample than in the control, or less.

3. Method for in vitro detection of severe sepsis,

characterized in that

it comprises the following steps:

m)   Isolation of sample RNA from a sample of a mammal;

n)   Labelling of the sample RNA and/or at least one DNA being a gene or gene fragment specific for severe sepsis, with a detectable label.

o)   Contacting the sample RNA with the DNA under hybridization conditions;

p)   Contacting sample RNA representing a control for non-pathologic conditions, with at least one DNA, under hybridization conditions, whereby the DNA is a gene or gene fragment specific for severe sepsis;

q)   Quantitative detection of the label signals of the hybridized sample RNA and control RNA;

r)   Comparing the quantitative data of the label signals in order to determine whether the genes or gene fragments specific for severe sepsis are more expressed in the sample than in the control, or less.

4. Method according to one of claims 1 to 3, characterized in that the control RNA is hybridized with the DNA before the measurement of the sample RNA and the label signals of the control RNA/DNA-complex is gathered and, if necessary, recorded in form of a calibration curve or table.

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5. Method according to one of claims 1 to 4, characterized in that unchanged genes from sample and/or control RNA are used as reference genes for the quantification.

10 6. Method according to one of claims 1 to 5, characterized in that mRNA is used as sample RNA.

7. Method according to one of claims 1 to 6, characterized in that the DNA is arranged, particularly immobilized, on predetermined areas on a carrier in the 15 form of a microarray.

8. Method according to one of claims 1 to 7, characterized in that the method for early detection by means of differential diagnostics, for control of the clinical and therapeutic progress, for the individual risk evaluation in patients, for the 20 evaluation whether the patient will respond to a specific treatment, as well as for post mortem diagnosis of SIRS and/or sepsis and/or severe sepsis and/or systemic infections and/or septic conditions and/or infections.

9. Method according to one of claims 1 to 8, characterized in that the sample is 25 selected from the following group: body fluids, in particular blood, liquor, urine, ascitic fluid, seminal fluid, saliva, puncture fluid, cell content, or a mixture thereof.

10. Method according to one of claims 1 to 9, characterized in that cell samples 30 are subjected a lytic treatment, if necessary, in order to free their cell contents.

11. Method according to one of claims 1 to 10, characterized in that the mammal is a human.

35 12. Method according to one of claims 1 or 4 to 11, characterized in that the gene or gene segment specific for SIRS is selected from the group consisting of SEQUENCE ID No. III.1 to SEQUECE ID No. III.4168, as well as gene fragments thereof with 5-2000 or more, preferably 20-200, more preferably 20-80 nucleotides.

13. Method according to one of claims 2 or 4 to 11, characterized in that the gene or gene segment specific for sepsis and/or sepsis-like conditions is selected from the group consisting of SEQUENCE ID No. I.1 to SEQUECE ID No. I.6242, as well as gene fragments thereof with 5-2000 or more, preferably 20-200, more preferably 20-80 nucleotides.

14. Method according to one of claims 3 or 4 to 11, characterized in that the gene or gene segment specific for severe sepsis is selected from the group consisting of SEQUENCE ID No. II.1 to SEQUECE ID No. II.130, as well as gene fragments thereof with 5-2000 or more, preferably 20-200, more preferably 20-80 nucleotides.

15. Method according to one of claims 1 to 14, characterized in that at least 2 to 100 different cDNAs are used.

16. Method according to one of claims 1 to 15, characterized in that at least 200 different cDNAs are used.

17. Method according to one of claims 1 to 16, characterized in that at least 200 to 500 different cDNAs are used.

18. Method according to one of claims 1 to 17, characterized in that at least 500 to 1000 different cDNAs are used.

19. Method according to one of claims 1 to 18, characterized in that at least 1000 to 2000 different cDNAs are used.

20. Method according to one of claims 1 to 19, characterized in that the cDNA of the genes listed in claims 12, 13 und 14 is replaced by synthetic analoga as well as peptidonucleic acids.

21. Method according to claim 20, characterized in that the synthetic analoga of the listed genes comprise 5-100, in particular approximately 70, base pairs.

22. Method according to one of claims 1 to 21, characterized in that a radioactive label, in particular ^{32}P, ^{14}C, ^{125}I, ^{155}Ep, ^{33}P or ^{3}H is used as detectable label.

23.   Method according to one of claims 1 to 22, characterized in that a non-radioactive label is used as detectable label, in particular a color- or fluorescence label, an enzyme label or immune label, and/or quantum dots or an electrically measurable signal, in particular the change in potential, and/or conductivity and/or capacity by hybridizations.

24.   Method according to one of claims 1 to 23, characterized in that the sample RNA and control RNA bear the same label.

25.   Method according to one of claims 1 to 24, characterized in that the sample RNA and control RNA bear different labels.

26.   Method according to one of claims 1 to 25, characterized in that the immobilized probes bear a label.

27.   Method according to one of claims 1 to 26, characterized in that the cDNA probes are immobilized on glass or plastics.

28.   Method according to one of claims 1 to 27, characterized in that the individual cDNA molecules are immobilized on the carrier material by means of a covalent binding.

29.   Method according to one of claims 1 to 28, characterized in that the individual cDNA molecules are immobilized onto the carrier material by means of adsorption, in particular by means of electrostatic and/or dipole-dipole and/or hydrophobic interactions and/or hydrogen bridges.

30.   Method for in vitro detection of SIRS,

characterized in that

it comprises the following steps:

a) Isolation of sample peptides from a sample of a mammal;

b) Labelling of the sample peptides with a detectable label;

c) Contacting the labelled sample peptides with at least one antibody or its binding fragment, whereby the antibody binds a peptide or peptide fragment specific for SIRS;

5 d) Contacting the labelled control peptides originating from healthy subjects, with at least one antibody or its binding fragment immobilized on a carrier in form of a microarray, whereby the antibody binds a peptide or peptide fragment specific for SIRS;

10 e) Quantitative detection of the label signals of the sample peptides and the control peptides;

f) Comparing the quantitative data of the label signals in order determine whether the genes or gene fragments specific for SIRS are more expressed in the
15 sample than in the control, or less.

31. Method for in vitro detection of sepsis and/or sepsis-like conditions,

characterized in that

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it comprises the following steps:

g) Isolation of sample peptides from a sample of a mammal;

25 h) Labelling of the sample peptides with a detectable label;

i) Contacting the labelled sample peptides with at least one antibody or its binding fragment, whereby the antibody binds a peptide or peptide fragment specific for sepsis and/or sepsis-like conditions;

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j) Contacting the labelled control peptides stemming from healthy subjects, with at least one antibody or its binding fragment immobilized on a carrier in form of a microarray, whereby the antibody binds a peptide or peptide fragment specific for sepsis and/or sepsis-like conditions;

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k) Quantitative detection of the label signals of the sample peptides and the control peptides;

l) Comparing the quantitative data of the label signals in order to be able to determine whether the genes or gene fragments specific for sepsis and/or sepsis-like conditions are more expressed in the sample than in the control, or less.

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32.   Method for in vitro detection of severe sepsis,

characterized in that

10   it comprises the following steps:

m)   Isolation of sample peptides from a sample of a mammal;

n) Labelling of the sample peptides with a detectable label;

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o) Contacting the labelled sample peptides with at least one antibody or its binding fragment, whereby the antibody binds a peptide or peptide fragment specific for severe sepsis;

20 p) Contacting the labelled control peptides originating from healthy subjects, with at least one antibody or its binding fragment immobilized on a carrier in form of a microarray, whereby the antibody binds a peptide or peptide fragment specific for severe sepsis;

25 q) Quantitative detection of the label signals of the sample peptides and the control peptides;

r) Comparing the quantitative data of the label signals in order to determine whether the genes or gene fragments specific for severe sepsis are more 30 expressed in the sample than in the control, or less.

33. Method according to one of claims 30 to 32, characterized in that the antibody is immobilized on an array in form of a microarray.

35 34.   Method according to one of claims 30 to 33, characterized in that it is formed as immunoassay.

35.   Method according to one of claims 30 to 34, characterized in that the method is used for early detection by means of differential diagnostics, for

control of the clinic and therapeutic progress, for risk evaluation for patients as well as for post mortem diagnosis of SIRS and/or sepsis and/or severe sepsis and/or systemic infections and/or septic conditions and/or infections.

36. Method according to one of claims 30 to 35, characterized in that the sample is selected from the following group: body fluids, in particular blood, liquor, urine, ascitic fluid, seminal fluid, saliva, puncture fluid, cell content, or a mixture thereof.

37. Method according to one of claims 30 to 36, characterized in that cell samples are subjected a lytic treatment, if necessary, in order to free their cell contents.

38. Method according to one of claims 30 to 37, characterized in that the mammal is a human.

39. Method according to one of claims 30 or 33 to 38, characterized in that the peptide specific for SIRS is an expression product of a gene or gene fragment selected from the group consisting of SEQUENCE ID No. III.1 to SEQUECE ID No. III.4168, as well as gene fragments thereof with 5-2000 nucleotides or more, preferably 20-200, more preferable 20-80 nucleotides.

40. Method according to one of claims 31 or 33 to 38, characterized in that the peptide specific for sepsis and/or sepsis-like conditions is an expression product of a gene or gene fragment selected from the group consisting of SEQUENCE ID No. I.1 to SEQUECE ID No. I.6242, as well as gene fragments thereof with 5-2000 nucleotides or more, preferably 20-200, more preferable 20-80 nucleotides.

41. Method according to one of claims 32 or 33 to 38, characterized in that the peptide specific for severe sepsis is an expression product of a gene or gene fragment selected from the group consisting of SEQUENCE ID No. II.1 to SEQUECE ID No. II.130, as well as gene fragments thereof with 5-2000 or more, preferably 20-200, more preferably 20-80 nucleotides.

42. Method according to one of claims 30 to 41, characterized in that at least 2 to 100 different peptides are used.

43. Method according to one of claims 30 to 42, characterized in that at least 200 different peptides are used.

44. Method according to one of claims 30 to 43, characterized in that at least 200 to 500 different peptides are used.

45. Method according to one of claims 30 to 44, characterized in that at least 500 to 1000 different peptides are used.

46. Method according to one of claims 30 to 45, characterized in that at least 1000 to 2000 different peptides are used.

47. Method according to one of claims 30 to 46, characterized in that a radioactive label, in particular ^{32}P, ^{14}C, ^{125}I, ^{155}Ep, ^{33}P or ^{3}H is used as detectable label.

48. Method according to one of claims 30 to 47, characterized in that a non-radioactive label is used as detectable label, in particular a color- or fluorescence label, an enzyme label or immune label, and/or quantum dots or an electrically measurable signal, in particular the change in potential, and/or conductivity and/or capacity by hybridizations.

49. Method according to one of claims 30 to 48, characterized in that the sample peptides and control peptides bear the same label.

50. Method according to one of claims 30 to 49, characterized in that the sample peptides and control peptides bear different labels.

51. Method according to one of claims 30 to 50, characterized in that the probes used are peptides to which labelled antibodies are bound, which cause a change of signal of the labelled antibodies by change of conformation when binding to the sample peptides.

52. Method according to one of claims 30 to 51, characterized in that the peptide probes are immobilized on glass or plastics.

53.   Method according to one of claims 30 to 52, characterized in that the individual peptide molecules are immobilized onto the carrier material by means of a covalent binding.

5 54.   Method according to one of claims 30 to 53, characterized in that the individual peptide molecules are immobilized on the carrier material by means of adsorption, in particular by means of electrostatic and/or dipole-dipole and/or hydrophobic interactions and/or hydrogen bridges.

10 55.   Method according to one of claims 30 to 54, characterized in that the individual peptide molecules are detected by means of monoclonal antibodies or their binding fragments.

56.   Method according to one of claims 30 to 55, characterized in that the determination of individual peptides by means of immunoassay or precipitation assay is carried out using monoclonal antibodies.

57.   Use of recombinantly or synthetically produced SIRS-specific nucleic acid sequences, partial sequences or protein-/peptide-sequences derived thereof, individually or as partial quantities as calibrator in SIRS-assays and/or to evaluate the effects and toxicity when screening for active agents and/or for the preparation of therapeutics as well as of substances and compounds that are designed to act as therapeutics, for the prevention and treatment of SIRS.

25 58.   Use of recombinantly or synthetically produced sepsis-specific and/or sepsis-like conditions-specific nucleic acid sequences, partial sequences or protein-/peptide-sequences derived thereof, individually or as partial quantities as calibrator in sepsis assays and/or to evaluate the effects and toxicity when screening for active agents and/or for the preparation of therapeutics as well as of substances and compounds that are designed to act as therapeutics, for the prevention and treatment of sepsis, sepsis-like systemic inflammatory conditions and sepsis-like systemic infections.

59.   Use of recombinantly or synthetically produced severe sepsis-specific nucleic acid sequences, partial sequences or protein-/peptide-sequences derived thereof, individually or as partial quantities as calibrator in sepsis-assays and/or to evaluate the effects and toxicity when screening for active agents and/or for the preparation of therapeutics as well as of substances and

compounds that are designed to act as therapeutics, for the prevention and treatment of severe sepsis.